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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,053	06/10/2002	Thomas D. Schneider	4239-62263	9108
36218	7590	11/04/2004		
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET, SUITE #1600 ONE WORLD TRADE CENTER PORTLAND, OR 97204-2988				
EXAMINER STRZELECKA, TERESA E				
ART UNIT			PAPER NUMBER	
1637				

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/070,053

**Applicant(s)**

SCHNEIDER ET AL.

**Examiner**

Teresa E Strzelecka

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29,35,36,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4 is/are rejected.
- 7) ☒ Claim(s) 3,5-12,17,19-29,35,36,46 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>22102004</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/28/02, 7/30/04, 9/21/04; 10/05/04</u> | 6) <input checked="" type="checkbox"/> Other: <u>Notice to Comply</u> .  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I (claims 1-29, 35, 36, 46 and 47) and species A (claims 11 and 12) in the reply filed on July 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-33, 35-43, 46 and 47 were previously pending. Applicants cancelled claims 30-33 and 37-43, therefore only the elected claims, 1-29, 35, 36, 46 and 47, are pending.
3. Claims 13-16 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 30, 2004.
4. Claims 1-12, 17, 19-29, 35, 36, 46 and 47 will be examined.

### ***Information Disclosure Statement***

5. The information disclosure statements (IDS) submitted on February 28, 2002, July 30, 2004, September 21, 2004 and October 5, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Sequence Rules Compliance***

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the

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requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN time of response to this office action WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

On page 27, lines 19, 21 and 23 there are three nucleic acid sequences which do not have SEQ ID NOs and no sequence listing in either paper or electronic form has been filed.

#### ***Claim Interpretation***

7. The term “sequencing a nucleic acid” is not defined by Applicants, and it is interpreted as incorporation of at least one nucleotide into the strand being synthesized by a polymerase.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (Biochemistry, vol. 28, pp. 9568-9593, 1989; cited in the IDS filed February 28, 2002).

Regarding claim 1, Allen et al. teach a method of sequencing a sample nucleic acid molecule, the method comprising:

exposing the sample nucleic acid molecule to an oligonucleotide primer and a polymerase in the presence of a mixture of nucleotides, wherein the polymerase and the nucleotides each comprise a fluorophore which emits a signal corresponding to addition of a particular nucleotide as each nucleotide is incorporated into a synthesized nucleic acid molecule which is complementary to the sample nucleic acid molecule (Allen et al. teach exposing a sample nucleic acid molecule of 20 bp to an 11 bp oligonucleotide primer in the presence of dNTPs (page 9587, fifth paragraph; page 9588, third paragraph). The polymerase was labeled with an NBD (4-[N-[(iodoacetoxy)ethyl]-N-methylamino]-7-nitrobenz-2-oxa-1,3-diazole) fluorophore and the nucleotides were labeled with ANS (aminophthalenesulfonates) fluorophores (Abstract; page 9587, first, seventh and ninth paragraphs). The nucleotides (dUTPs) emitted a signal which corresponded to addition of the nucleotide as the nucleotide was incorporated into the nucleic acid molecule (Fig. 4).); and

detecting the signal as each nucleotide is incorporated into the synthesized nucleic acid molecule (Allen et al. teach detecting the signal from the nucleotides (Fig. 4).).

Regarding claim 2, Allen et al. teach a DNA polymerase (Abstract; page 9587, first paragraph).

Regarding claim 4, Allen et al. teach a Klenow fragment of DNA polymerase I (Abstract; page 9587, first paragraph).

#### ***Allowable Subject Matter***

10. No references were found teaching or suggesting claims 3, 5-12, 17, 19-29, 35, 36, 46 and 47. The closest prior art reference, Chan (U.S. Patent No. 6,210,896 B1), teaches sequencing of nucleic acids using a fluorescently-labeled polymerase and fluorescently-labeled template, but does not teach or suggest fluorescently-labeled nucleotides.

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11. Claims 3, 5-12, 17, 19-29, 35, 36, 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teresa E Strzelecka  
*Teresa Strzelecka*  
Examiner  
Art Unit 1637

October 22, 2004